[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Linco-Feed 110 mg/g premix for medicated feeding stuff for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g product contains:
Active substance:
Lincomycin (as hydrochloride) 110 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
White or almost white granules.

4. CLINICAL PARTICULARS

4.1 Target species

Swine.

4.2 Indications for use, specifying the target species

For treatment of swine dysentery caused by *Brachyspira hyodysenteriae*, mycoplasmal pneumonia associated with *Mycoplasma hyopneumoniae* and porcine proliferative enteropathy (ileitis) associated with *Lawsonia intracellularis*.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipient.
Do not use in horses, ruminants, rabbits, guinea pigs and hamsters.
Do not use if resistance to lincosamides has been detected.

4.4 Special warnings for each target species

Inappropriate use of the product may increase the prevalence of bacteria resistant to lincosamides.
Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. The presence of the indicated diseases in the herd should be established before use.

4.5 Special precautions for use

Special precautions for use in animals

Medicated feeding stuff uptake can be affected by the severity of the disease. In case of insufficient uptake of feed, animals should be treated parenterally.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to lincomycin should avoid contact with the veterinary medicinal product.
Care should be taken not to inhale any dust. The wearing of approved dust masks (either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to

European Standard EN 140 with a filter to EN 143), gloves, overalls and safety glasses is recommended during the handling and mixing of this product.
Direct contact of the product with the skin, eyes and mucous membranes should be avoided.
In case of accidental exposure rinse abundantly with water. In case of allergic reaction (inflammation of the face, lips or eyes or respiratory difficulties) during handling or mixing of the product, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not smoke, eat or drink when handling the product.
Wash hands and any exposed skin with soap and water immediately after use.

When spreading the manure of weaner pigs treated with the veterinary medicinal product at a dose of 10 mg/kg for 21 days, a minimum distance to surface water of 10 m should be applied.

4.6 Adverse reactions (frequency and seriousness)

Lincomycin may occasionally cause transient soft stools and/or mild swelling of the anus within the first two days of treatment. Very rarely some pigs may show skin reddening and mildly irritable behaviour. These conditions are usually self-correcting within 5-8 days without discontinuing lincomycin treatment.

4.7 Use during pregnancy, lactation or lay

The safety of the product has not been established in pregnant or lactating sows. Use only in accordance with risk/benefit assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Co-administration with macrolides (e.g. erythromycin) should be avoided.

4.9 Amounts to be administered and administration route

To be administered orally, in dry medicated feeding stuff.

Indication	***Treatment (mg/kg feed)***	
	Product	***Lincomycin***
Swine dysentery	1000	110
Mycoplasma pneumonia	2000	220
Proliferative enteropathy	2000	220

Treatment of swine dysentery:
Feed 110 mg lincomycin/kg complete feed (equivalent to 5.5 mg lincomycin/kg bodyweight) as the sole ration for three weeks or until clinical signs of disease (watery, mucoid or bloody stools) disappear.

Treatment of mycoplasmal pneumonia:
Feed 220 mg lincomycin/kg complete feed (equivalent to 11 mg lincomycin/kg bodyweight) as the sole ration for three weeks or until clinical signs of disease disappear.

Treatment of porcine proliferative enteropathy:
Feed 220 mg lincomycin/kg complete feed (equivalent to 11 mg lincomycin/kg bodyweight) as the sole ration for three weeks.

Medicated feed may be pelleted at temperatures not exceeding 85ºC.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In pigs treated with 2-10 times the recommended dose orally for 14 days altered the stool consistency, from loose stool to diarrhoea, without the loss of appetite.
If suspected toxic reactions occur due to overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

4.11 Withdrawal period(s)

Swine: Meat and offal: 5 days.

5. <PHARMACOLOGICAL><IMMUNOLOGICAL> PROPERTIES

Pharmacotherapeutic group: lincosamides.
ATC vet code: QJ01FF02.

5.1 Pharmacodynamic properties

Lincomycin is a lincosamide antibiotic produced by Streptomyces lincolensis. Lincomycin is bacteriostatic in action inhibiting the protein synthesis predominantly by binding to the 50S ribosomal subunits of bacteria.
Depending on the sensitivity of micro-organisms, and on the concentration of the active substance the protein synthesis inhibition antibacterial action can either be bacteriostatic or bactericide.
Lincomycin is active against a wide range of Gram-positive bacteria, such as staphylococci, streptococci, β-haemolytic streptococci, corynebacteria, Erysipelothrix spp., and anaerobic bacteria, such as clostridia, Bacteroides spp., Brachyspira spp., as well as Leptospira spp. and Mycoplasma spp.
Lincomycin has no activity against Gram-negative bacteria, such as Klebsiella spp., Pasteurella spp., and Salmonella spp.
The resistance rate against lincomycin is slow, multiple-step type. Plasmid mediated infectious resistance is also described.
No cross-resistance has been described with penicillin, ampicillin, cephalosporins, tetracyclines, or novobiocin.
Lincomycin MIC_{90} (μg/ml) values are the followings:
Mycoplasma hyopneumoniae: MIC_{90} (μg/ml) = 0.25
Brachyspira hyodysenteriae: MIC_{90} (μg/ml) = 100

5.2 Pharmacokinetic particulars

Systemic bioavailability of lincomycin is approximately 53% after oral administration in pigs
Lincomycin is rapidly absorbed orally and reaches therapeutic plasma concentration.
After a single, oral administration of approximately 4.4 mg/kg and 11 mg/kg lincomycin to pigs resulted therapeutic plasma concentration for 12-16 hours, reaching peak plasma concentration after 4 hours. After a single, oral dose of 10 mg/kg lincomycin to pigs the maximum plasma concentration (C_{max}) of 1.45 mg/kg was reached at 3.6 hours (T_{max}). The elimination half life ($T_{1/2\beta}$) is about 3.36 hours. The oral administration of 22 mg/kg lincomycin for 3 days to pigs did not result in drug accumulation after 24 hours of administration and there was no therapeutic plasma concentration.
After oral administration the absorbed lincomycin is eliminated through the bile and faeces in active form or as metabolites.
Lincomycin is also *excreted* in the milk.
Lincomycin reaches the inflammation site by polymorf neutrophil granulocytes that explains its fast absorption and distribution, efficient penetration and targeted activity in difficult to reach tissues.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate.

6.2 Major incompatibilities

In absence of compatibility studies this product must not be mixed with other veterinary products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 3 months.
Shelf-life after incorporation into feed: 3 months.

6.4. Special precautions for storage

Store below 25ºC. Store in a dry place.
Store in the original container tightly closed after use in order to protect from moisture.

6.5 Nature and composition of immediate packaging

5 kg multiwalled, polyethylene layered paper bag.
10 kg multiwalled, polyethylene layered paper bag.
25 kg multiwalled, polyethylene layered paper bag.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Lavet Pharmaceuticals Ltd.
2143 Kistarcsa
Batthyany u. 6.
Hungary

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

5 kg multiwalled, polyethylene layered paper bag.
10 kg multiwalled, polyethylene layered paper bag.
25 kg multiwalled, polyethylene layered paper bag.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Linco-Feed 110 mg/g premix for medicated feeding stuff for pigs
Lincomycin (as hydrochloride)

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Lincomycin (as hydrochloride) 110 mg/g

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. PACKAGE SIZE

5 kg
10 kg
25 kg

5. TARGET SPECIES

Swine

6. INDICATION(S)

Swine: For treatment of swine dysentery caused by *Brachyspira hyodysenteriae*, mycoplasmal pneumonia associated with *Mycoplasma hyopneumoniae* and porcine proliferative enteropathy (ileitis) associated with *Lawsonia intracellularis*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To be administered orally, in dry medicated feeding stuff.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings:
People with known hypersensitivity to lincomycin should avoid contact with the veterinary medicinal product.
Wear protective gloves, overalls, safety glasses and dust mask when handling and mixing the product.
Read package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 3 months.
Shelf-life after incorporation into feed: 3 months.
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Store below 25ºC. Store in a dry place.
Store in the original container tightly closed after use in order to protect from moisture.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Lavet Pharmaceuticals Ltd.
2143 Kistarcsa
Batthyany u. 6.
Hungary

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Linco-Feed 110 mg/g premix for medicated feeding stuff for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Lavet Pharmaceuticals Ltd., 2143 Kistarcsa, Batthyány u. 6, Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Linco-Feed 110 mg/g premix for medicated feeding stuff for pigs
Lincomycin (as hydrochloride)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each kg product contains:
Active substance:
Lincomycin (as hydrochloride) 110 g
White or almost white granules.

4. INDICATION(S)

Swine: For treatment of swine dysentery caused by *Brachyspira hyodysenteriae*, mycoplasmal pneumonia associated with *Mycoplasma hyopneumoniae* and porcine proliferative enteropathy (ileitis) associated with *Lawsonia intracellularis*.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to the excipient.
Do not use in horses, ruminants, rabbits, guinea pigs and hamsters.
Do not use if of resistance to lincosamides has been detected.

6. ADVERSE REACTIONS

Lincomycin may occasionally cause transient soft stools and/or mild swelling of the anus within the first two days of treatment. Very rarely some pigs may show skin reddening and mildly irritable behaviour. These conditions are usually self-correcting within 5-8 days without discontinuing lincomycin treatment.

7. TARGET SPECIES

Swine.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

To be administered orally, in dry medicated feeding stuff.

Indication	***Treatment (mg/kg feed)***	
	Product	***Lincomycin***
Swine dysentery	137,5	110

Mycoplasma pneumonia	275	220
Proliferative enteropathy	275	220

9. ADVICE ON CORRECT ADMINISTRATION

Treatment of swine dysentery:
Feed 110 mg lincomycin/kg complete feed (equivalent to 5.5 mg lincomycin/kg bodyweight) as the sole ration for three weeks or until clinical signs of disease (watery, mucoid or bloody stools) disappear.
Treatment of mycoplasmal pneumonia:
Feed 220 mg lincomycin/kg complete feed (equivalent to 11 mg lincomycin/kg bodyweight) as the sole ration for three weeks or until clinical signs of disease disappear.
Treatment of porcine proliferative enteropathy:
Feed 220 mg lincomycin/kg complete feed (equivalent to 11 mg lincomycin/kg bodyweight) as the sole ration for three weeks.
Medicated feed may be pelleted at temperatures not exceeding 85ºC.

10. WITHDRAWAL PERIOD(S)

Meat and offal of swine: 5 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 25ºC. Store in a dry place.
Keep the plastic container tightly closed, or re-close the paper bag mechanically as much as possible.
Store in the original container tightly closed after use in order to protect from moisture.
Shelf-life after first opening the immediate packaging: 3 months.
Shelf-life after incorporation into feed: 3 months.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Inappropriate use of the product may increase the prevalence of bacteria resistant to lincosamides.
Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. The presence of the indicated diseases in the herd should be established before use.

Special precautions for use in animals:
Medicated feeding stuff uptake can be affected by the severity of the disease. In case of insufficient uptake of feed, animals should be treated parenterally.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to lincomycin should avoid contact with the veterinary medicinal product.
Care should be taken not to inhale any dust. The wearing of approved dust masks (either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143), gloves, overalls and safety glasses is recommended during the handling and mixing of this product.
Direct contact of the product with the skin, eyes and mucous membranes should be avoided.

In case of accidental exposure rinse abundantly with water. In case of allergic reaction (inflammation of the face, lips or eyes or respiratory difficulties) during handling or mixing of the product, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not smoke, eat or drink when handling the product.
Wash hands and any exposed skin with soap and water immediately after use.

Pregnancy and lactation:
The safety of the product has not been established in pregnant or lactating sows. Use only in accordance with risk/benefit assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Co-administration with macrolides (e.g. erythromycin) should be avoided. In absence of compatibility studies this product must not be mixed with other veterinary products.

Overdose (symptoms, emergency procedures, antidotes):
In pigs treated with 2-10 times the recommended dose orally for 14 days altered the stool consistency, from loose stool to diarrhoea, without the loss of appetite.
If suspected toxic reactions occur due to overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

When spreading the manure of weaner pigs treated with the veterinary medicinal product at a dose of 10 mg/kg for 21 days, a minimum distance to surface water of 10 m should be applied.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For animal treatment only - to be supplied only on veterinary prescription.
Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

Pack sizes
5 kg multiwalled, polyethylene layered paper bag.
10 kg multiwalled, polyethylene layered paper bag.
25 kg multiwalled, polyethylene layered paper bag.
Not all pack sizes may be marketed.

In Italy:
Pharmacotherapeutic group: lincosamides, ATCvet code: QJ01FF02.

In the United Kingdom:
When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.